## **REMARKS/ARGUMENTS**

Claim 19 is pending.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and

the following remarks.

Reconsideration of the restriction requirement is respectfully requested.

The Examiner sets forth that although the attorney of record and the Examiner had agreed

to give favorable consideration to new claim 19, a final review of the case indicates to the Examiner

that a 103 rejection of claim 19 is appropriate. The Examiner apologizes for any inconveniences

incurred by the attorney or the applicant because of this decision.

The Examiner further sets forth that claim 19 is rejected under 35 U.S.C. 103(a) as being

unpatentable over Keeton.

According to the Examiner Keeton discloses in figures 3-4 a method of providing a pre-

surgical warning for use on a body comprising placing a label 40 on the body, providing a visually

perceivable indicator 42 on the label, attaching the label to the body. The Examiner believes that

the label has an inferior (the side attached to the body) and a superior side (the side with the writing

on it). However, the Examiner sets forth that Keeton doesn't disclose attaching the label to surgical

sites that are unintended surgical sites. According to the Examiner it would have been obvious to

one having ordinary skill in the art that the label disclosed by Keeton could be attached to any body

portion. Thus, the Examiner sets forth that if the medical attendant intends on the body portion being

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a site on the body that is not being operated on, that is a matter of choice as to where to attach the

label.

Keeton teaches surgical clothing and labeling means for protection of a patient entering

surgery. The system taught by Keeton includes both a gown and labels. The gown is made of a

disposable material so that the gown as a whole can remain in place on the patient while portions

thereof are cut away to allow required access to the body. The labels taught by Keeton designate an

area of an intended surgical operation.

Keeton makes a number of references to the placement of the indicator. For example:

Furthermore it is contemplated that the labeling means will be used on

the patient, to designate the area for the intended surgery. Labeling

means may take the form of a single label for recording required

information, along with arrows or directed means to indicate the

specific location of the surgery. (emphasis added) (Col. 2, lines 31-36)

Additionally, Keeton teaches that:

... it will be seen that the label 31 is an arrow pointing to the right

shoulder of the patient. By way of example, if the label 30 indicates

that the patient is to under go an operation on the shoulder, the label

31 assists in directing attention to the proper shoulder. (emphasis

added) (Col. 3, line 68 - Col.4, line 4)

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Further, Keeton sets forth:

... there is an additional label 41 constituting directing means <u>for</u> directing attention to the right eye of the patient. (emphasis added) (Col. 4, lines 39-41)

In another teaching with respect to the location of the directing means, Keeton teaches,

. . . the written material 42 would carry the general information required and the directing means indicated at 44 would <u>point</u> <u>precisely to the cite of operation</u>. (emphases added) (Col. 4, lines 52-55).

Thus, in each of the foregoing cites, <u>Keeton explicitly teaches indicating the intended site</u> rather than the unintended site. Such teachings do not provide any suggestion whatsoever that the label disclosed by Keeton should be attached to any arbitrarily chosen site on the patient, as set forth by the Examiner. To interpret the foregoing as suggestions to indicate the unintended site one must use impermissible hindsight. <u>In fact, these teachings teach away from the unintended site</u> by repeatedly and explicitly teaching the use of the label at the intended site.

Additionally, Fig. 3 represents only intended site placement. At a single location in the specification Keeton discusses the location of the label without explicitly stating that the location should be at the intended site. This occurs at column 2, lines 36-39 wherein Keeton teaches that "additional labels may indicate directions and/or locations." This one citation cannot, even if taken by itself, be construed to suggest indicating an unintended site since no such location is set forth.

This is especially true in the context in which all of the other references are explicitly directed to the

intended site. This citation merely appears to mean that surgery can take place on two or more sites,

each site being indicated by an intended site label. It would be inviting catastrophe to have two

different labels on a patient with two different conventions, one pointing to the intended site and one

pointing to an unintended site.

Thus, Keeton does not teach or suggest attaching an indicator label pointing to an unintended

site as required in the Applicant's claim 19. Rather, Keeton teaches away from attaching the

indicator means to an unintended site, taken as a whole.

Further support for the Applicant's position is set forth in an Affidavit under 37 CFR 1.132

filed herewith. In this Affidavit, the Applicant avers facts under oath showing that there was a long

felt need for the invention since there was substantially no market for a wrong site surgery prevention

labels that indicated the unintended site at the time that the invention was made, and that such labels

have fluctuated between ten and twenty per cent of the market in wrong site surgery prevention

labels since the time of the invention.

Furthermore, all relevant references cited by the Examiner or known to the Applicant teach

pointing to the intended site, further teaching away from the Applicant's invention. It is well known

that proceeding contrary to common wisdom is evidence of unobviousness.

For at least the reasons set forth above, it is respectfully submitted that the above-identified

application is in condition for allowance. Favorable reconsideration and prompt allowance of the

claims are respectfully requested.

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Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD.

August 16, 2005

Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.

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